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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,673

10/15/2002

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/069,673

Applicant(s)

EKHART ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/18/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/18/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The response filed on January 18, 2006 have been received and entered into the application.

Action Summary

The objection of claims 5-8 under 37 CFR 1.75(c) as being in improper multiple dependent form is hereby expressly withdrawn in view of Applicants' preliminary amendment filed on Feb 22, 2002.

Upon further consideration of Applicants' submission of translation of previously cited prior art (Lur'e et al.), the examiner has modified the rejections to better to advance prosecution. Because the references are being used to reject claims different than the previous Office Action, instant Office Action is made non-final.

The rejection of claims 1- 10 under 35 U.S.C. 103(a) as being unpatentable over Lur'e et al. (Meditinskaya Parazitologiya I Parazitarnye Bolezni (1987, abstract) in view of Dick et al. (FR 2336931) of record is moot in view of instant Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 9, the term "through" is vague and renders the claims indefinite because it suggests a water distribution system as a device rather than a water supply, for example "a tube". Does Applicant intend "using" or "with"?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1- 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dick et al. (FR 2336931) of record in view of Lur'e et al. (Meditsinskaya Parazitologiya I Parazitarnye Bolezni (1987, abstract).

Dick et al. teach that new pharmaceutical compositions containing mebendazole can be formulated in suspensions comprising water and can be added to an animal feed or drinking water. (abstract). Dick et al. teach compositions comprising mebendazole, water, glycerin (water-immiscible liquid), and stabilizing agents. (page 6, example 6). Dick et al. teach that compositions can be administered orally to animals in liquid formulation. (page 2, lines 25-33).

Dick et al. do not teach the specified density and the specified ratio set forth in claims 4 and 9, and the particle size set forth in claim 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made prepare Dick et al's composition for veterinary use through a water distribution system because Dick et al. teaches that mebendazole composition can be administered to animals in a liquid formulation and because Dick et al. teach that compositions can be added to an animal feed or drinking water. One would have been motivated to add the Dick et al's composition in animal drinking water in order to

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advantageously administer mebendazole liquid formulation while satisfying the thrusts. There is a reasonable expectation of successfully administering mebendazole liquid formulation of Dick et al. utilizing water distribution system such as water supply because Dick et al. teaches that the composition comprising mebendazole can be administered successfully in drinking water. The ratios of active agents to be used, the density the pharmaceutical forms, e.g., suspoemulsion, emulsion, etc; mode of administration, the specific particle size are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and it is within the general practice to discover the optimum or workable ranges involves only routine skill in the art. Further, Dick et al. teaches the composition comprising same components as the composition utilized in the instant claim 1. Therefore, it would be obvious to one of ordinary skill in the art that the composition taught by Dick et al. would have the same density as set forth in claim 1 because the compound and all of its properties are inseparable; they are one and the same thing. In re Papesch, 315 F2d 381, 391 (C.C.P.A. 1963).

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dick et al. (FR 2336931) of record in view of Lur'e et al. (Meditsinskaya Parazitologiya I Parazitarnye Bolezni (1987, abstract).

Dick et al. as applied as before.

Lur'e et al. teach that mebendazole (a benzimidazole active compound) can be formulated with sunflower, corn, mustard, olive or apricot oils. Lur'e et al. teach that the

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sunflower oil was the most effective vehicle and it increased bioavailability and prolonged the maintenance of therapeutic levels of mebendazole in the blood of experimental mice. (abstract).

Lur'e et al. does not teach the specified density and the specified ratio set forth in claim 10.

It would have been obvious to one of ordinary skill in the art to formulate the formulation comprising mebendazole and sunflower oil with optimizing ratios in any formulation. One would have been motivated to make such a modification since the formulation taught by Lur'e et al. prolonged the maintenance of therapeutic levels of active compound (mebendazole) in mice experimentation as taught by Lur'e et al. and because benzimidazole compounds (e.g. mebendazole) are well-known to be combined with water to formulate a suspension as taught by Dick et al. The range of density is obvious because Lur'e et al teaches the composition comprising mebendazole and various vegetable oil. This is so, because similar compositions will have overlapping physical properties such as density. The ratios of active agents to be used, the pharmaceutical forms, e.g., suspoemulsion, emulsion, etc; mode of administration, flavors, carriers, particle size and surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and it is within the general practice to discover the optimum or workable ranges involves only routine skill in the art. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Response to Arguments

Applicants' arguments have been fully considered but they are not persuasive. Applicants argue that Lur'e et al. describe formulations of mebendazole in a vegetable oil but these oily formulations of mebendazole do not comprise water. This is not found persuasive because Dick et al. teach that mebendazole can be formulated in suspensions comprising water and can be added to animal feed or drinking water. Dick et al. also teach that mebendazole can be formulated with glycerin (water-immiscible liquid) required by the instant claim 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer Dick et al.'s composition for veterinary use through a water distribution system because Dick et al. teach that mebendazole composition can be administered through their drinking water. Applicants argue that Lur'e et al. do not teach or suggest aqueous suspensions of mebendazole with vegetable oils. This is not found persuasive because Lur'e et al. teach that sunflower oil is the most effective vehicle and it increased bioavailability and prolongs the maintenance of therapeutic levels of mebendazole. Therefore, it would have been obvious to one of ordinary skill in the art to modify mebendazole formulation of Dick et al. and employ sunflower oil because sunflower oil increases bioavailability of mebendazole composition. One would have been motivated to make such a

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modification in order to achieve an expected benefit of increased bioavailability of mebendazole composition as taught by Lure'e et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

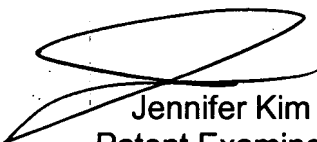
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jennifer Kim
Patent Examiner
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Jmk
August 2, 2007